K100352

Diagnosoft, Inc.
HARP 2.06
510(k) Summary
(per 21 CFR 807.92(c))

MAR 11 2010

1. SPONSOR/MANUFACTURER

Diagnosoft, Inc.
6501 Weston Parkway
Suite 125
Cary, NC 27513
Primary Contact: Linda Horne

Date Prepared: February 11, 2010

2. DEVICE NAME

Proprietary Name:	Diagnosoft HARP 2.06
Common/Usual Name:	HARP
Classification Name:	System, Image Processing, MRI Accessory

3. PREDICATE DEVICE

Predicate Device: Diagnosoft, Inc. HARP 1.1.0, K061368

4. DEVICE DESCRIPTION

The Diagnosoft, Inc. HARP 2.06 is intended for the quantification of regional and global cardiac function from magnetic resonance images. It includes a user friendly implementation of the HARP methods for fast and reproducible measuring of myocardial motion and strain in the heart. With a friendly graphic user interface, users are able to analyze tagged MR images in minutes and produce many measurements including strain, torsion, and regional wall thickening.

5. INDICATION FOR USE

The Diagnosoft, Inc. HARP 2.06 is a stand-alone software package which provides the capability to review, analyze, and report on magnetic resonance (MR) images. HARP can import images from an MR system and display them in a viewing area on the computer screen. Images can be organized and displayed by study and series and organized into

three-dimensional and temporal (multi-phase) collections. Temporal sequences can be displayed in a cine mode to facilitate visualization.

Tagged MR images can be imported, displayed, and analyzed. Available measurements include displacement, twist, and radial, circumferential, and principle strains. Tools are provided for display of regional motion properties of the heart.

A report interface is provided. Measurement tools provide information that can be output in standardized or specialized report formats. This interface makes it possible to quickly and reliably fill out a complete clinical report of an imaging exam. The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians in supporting the determination of a diagnosis.

6. Technological Characteristics and Substantial Equivalence

The modified Diagnosoft, Inc. HARP 2.06 is an upgrade of the predicate Diagnosoft, Inc. HARP 1.1.0. The modified Diagnosoft, Inc. HARP 2.06 is substantially equivalent to the predicate Diagnosoft, Inc. HARP 1.1.0 based on intended use, indications for use, operational characteristics, and fundamental technology characteristics. The performance specifications for the software characteristics performed by the HARP 2.06 are substantially equivalent to those of the HARP 1.1.0.

7. Performance Testing

Testing of the modified Diangosoft, Inc. HARP 2.06 has demonstrated that the device fulfills prospective defined performance criteria and that the modified device meets the user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Diagnosoft, Inc.
% Mr. Jeffrey Roberts
Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

MAR 11 2010

Re: K100352
Trade/Device Name: Diagnosoft, Inc. HARP 2.06
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 11, 2010
Received: February 12, 2010

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Diagnosoft, Inc. HARP 2.06

Indications for Use:

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Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100352